

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA

PROPYLENE OXIDE

Chemical Code # 508, Tolerance # 50582
SB 950 # 832

October 10, 1989
Revised 03/15/91

I. DATA GAP STATUS

Chronic toxicity, rat:	data gap, no study on file
Chronic toxicity, dog:	data gap, no study on file
Oncogenicity, rat:	no data gap, possible adverse effect
Oncogenicity, mouse:	no data gap, possible adverse effect
Reproduction, rat:	data gap, inadequate study, no adverse effect indicated
Teratology, rat:	data gap, inadequate study, no adverse effect indicated
Teratology, rabbit:	data gap, inadequate study, possible adverse effect indicated
Gene mutation:	no data gap, possible adverse effect

Chromosome effects:	no data gap, possible adverse effect
DNA damage:	no data gap, possible adverse effect
Neurotoxicity:	not required at this time

Toxicology one-liners are attached.

All record numbers through 090380 were examined.

** indicates an acceptable study.

Bold face indicates a possible adverse effect.

File name: T910315

Created by Stanton Morris, 03/15/91

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

Note: The possible routes of human exposure to propylene oxide are oral and inhalation and therefore CDFA requires adequate data to assess the hazards for both routes of exposure. There are currently no adequate pharmacokinetic data on file at CDFA to support a comparison of propylene oxide toxicity following oral and inhalation exposures. These data would be needed to support any request of bridging between routes.

CHRONIC TOXICITY, RAT

No study on file.

CHRONIC TOXICITY, DOG

No study on file.

ONCOGENICITY, RAT

**** 50582-001; 026429;** "NTP Technical Report on the Toxicology and Carcinogenesis Studies of Propylene Oxide in F344/N Rats and B6C3F₁ Mice (Inhalation Studies)", NTP TR 267, NIH Publication No. 85-2527, NTP-83-020; Battelle Northwest Laboratories; 03/85; propylene oxide, lot # 6477-22, 99.9%; Fifty rats / sex / dose were exposed by inhalation to 0, 200, or 400 ppm, 6 hours / day, 5 days / week for 103 weeks. Slightly-decreased body weights were seen in males at 400 ppm after week 20 and females after week 40. Possible adverse effects were indicated treatment-related increases in: pancreatic acinar cell atrophy in males at 200 and 400 ppm; cytomegaly in the adrenal cortex of females at 200 and 400 ppm; keratoacanthomas of the skin in males at 400 ppm; suppurative inflammation of the nasal cavity in both sexes at

200 and 400 ppm; and epithelial hyperplasia, squamous metaplasia, and papillary adenomas of the nasal cavity in both sexes at 400 ppm. The study is acceptable (S. Morris, 9/28/89).

50582-004; 041642; This document contains a draft of the two-year rat study in document at CDFA doc. # 50582-001, rec. # 026429. No worksheet was done (S. Morris, 06/13/89).

50582-007; 045504; This document contains an exact duplicate of CDFA doc. # 50582-001, rec. 026429. No worksheet was done (S. Morris, 07/28/89).

50582-005; 042521; "Chronic (28-month) inhalation toxicity/ carcinogenicity study of 1,2-propylene oxide in rats", report no. V 82.215/280853; CIVO Institutes (TNO), Zeist, Netherlands; 2/83; propylene oxide, 99.99 %; One hundred Wistar rats / sex / group were exposed by inhalation to 0, 30, 100, or 300 ppm for up to 28 months, 6 hours / day, 5 days / week. From each group, 10 rats / sex were sacrificed at 12, 18, and 24 months. Non-neoplastic, treatment-related effects were: slightly decreased body weight at 300 ppm; increased mortality in both sexes at 300 and in females at 100 ppm; and dose-related atrophy and hyperplasia of the olfactory epithelium in both sexes at 30, 100, and 300 ppm. **Possible adverse effects** were indicated by the following neoplastic effects: increased non-mammary tumors in both sexes at 300 ppm with no significant increase in any tumor type; increased mammary tubulopapillary carcinomas in females at 300 ppm; and dose-related increased incidence and multiplicity of mammary fibroadenomas in females at 30, 100, and 300 ppm. The study is unacceptable but provides useful data. The report is upgradeable as an oncogenicity study with submission of individual data (S. Morris, 09/26/89).

50582-004; 041629; This document contains a partial summary of the study at CDFA rec. # 50582-005, rec. # 042521. No worksheet was done (S. Morris, 06/13/89).

50582-007; 045503; "Carcinogenicity of ethylene oxide and 1,2-propylene oxide upon intragastric administration to rats"; Dunkelberg, H. (1982): Br. J. Cancer, 46:924-933; propylene oxide, 99% stated purity, in salad oil; Fifty female rats / group were dosed by oral gavage with 15 or 60 mg/kg, twice a week for the lifespans of the animals (\leq 150 weeks).

A possible adverse effect was indicated by reactive changes and carcinomas of the stomach's squamous epithelium at 15 and 60 mg/kg. The study is unacceptable because of many deviations from guidelines and not upgradeable because only one sex was used. The study has useful data (S. Morris, 10/02/89).

50582-004; 041638; This document contains a paragraph from the introduction of CDFA doc. # 50582-001, rec. # 026429. It is a summary of the study at CDFA doc. # 50582-001, rec. # 045503. No worksheet was done (S. Morris, 6/13/89).

50582-004; 041639; This document contains a paragraph from the introduction of CDFA doc. # 50582-001, rec. # 026429. It summarizes several studies in which possible adverse effects were indicated by tumors at subcutaneous injection sites in rats (Walpole, A. L. [1958]: Ann. N. Y. Acad. of Sci. 68:750-761) and mice (Dunkelberg H. [1979]: Br. J. Cancer, 39:588-589; [1981]: Zentralbl. Bakteriол. Mikrobiol. Hyg. (B), 174:383-404.), and mesotheliomas and gliomas in male F344 rats exposed to 50 or 100 ppm for two years (NIOSH [1983]: Preliminary results presented by T. Lewis at the Subcommittee on Environmental Mutagenesis, Bethesda, MD). CDFA requests that the registrant submit full reports of these studies for further evaluation. No worksheets were done (S. Morris, 6/13/89).

ONCOGENICITY, MOUSE

**** 50582-001; 026429;** "NTP Technical Report on the Toxicology and Carcinogenesis Studies of Propylene Oxide in F344/N Rats and B6C3F₁ Mice (Inhalation Studies)", NTP TR 267, NIH Publication No. 85-2527, NTP-83-020; Battelle Northwest Laboratories; 03/85; propylene oxide, lot # 6477-22, 99.9%; Fifty mice / sex / dose were exposed by inhalation to 0, 200, or 400 ppm, 6 hours / day, 5 days / week for 103 weeks. Treatment-related effects were: decreased body weights at 400 ppm in both sexes after week 29 and at 200 ppm in females after week 68; increased mortality in females at 200 ppm and in both sexes at 400 ppm; increased serous, suppurative, and acute/chronic inflammations of the nasal cavity at 200 and 400 ppm in both

sexes; increased hemangiomas and hemangiosarcomas of the nasal cavity at 400 ppm in both sexes; increases in ovarian atrophy, suppurative inflammation of the uterus, and mammary adenocarcinomas at 200 and 400 ppm in females. A possible adverse effect was indicated by the most significant findings: increased hemangiomas and hemangiosarcomas of the nasal cavity at 400 ppm. The study is acceptable (S. Morris, 10/02/89).

50582-004; 041643; This document contains a draft of the two-year mouse study in the document at CDFA doc. # 50582-001, rec. # 026429. No worksheet was done (S. Morris, 06/13/89).

50582-007; 045504; This document contains an exact duplicate of CDFA doc. # 50582-001, rec. 026429. No worksheet was done (S. Morris, 07/28/89).

REPRODUCTION, RAT

50582-023; 090379; "Effect of Inhaled Propylene Oxide on Reproductive Parameters in Fisher 344 Rats" by W.C. Hayes, H.D. Kirk, T.S. Gushow and J.T. Young; Dow Chemical Company, Midland, MI; propylene oxide, 99.7% stated purity; This was a two generation study with one litter per generation. Thirty adult Fisher 344 rats / sex / generation were exposed by inhalation to 0, 30, 100, or 300 ppm for 6 hours / day, 5 days / week (excluding holidays) until mating (f0 at 14 weeks, f1 at 17 weeks) then 7 days / week through lactation. F0 and f1 adults were respectively 7 and 3 weeks old at the start of exposures. Dams were not exposed on gestation day 21 through postpartum day 4. Pups were not exposed on postpartum days 0 through 28. Necropsies were performed on all f0 and f1 adults, and 10 f1 and 30 f2 pups / sex / exposure group. Histology was done on 10 f1 and f2 pups / sex of the 0 and 300 ppm groups. Treatment-related decreases in mean parental body weights were reported but mean parental weights for all treatment groups were within approximately 90% of controls at the time of mating. No other treatment-related clinical, gross or histo- pathological, or reproductive effects were reported. No adverse effect was indicated. The study was unacceptable because sufficient toxicity was not seen at the highest dose, pups were not exposed during lactation, necropsies

were not done on all pups, histopathology was done on no adult tissues and only on 10 f1 and f2 weanlings / sex / group from the 0 and 300 ppm groups. Individual data, lot number, and GLP sheets were also missing. The study is possibly upgradeable with submission of adequate rationales for the doses used, dosing protocol, and missing data (S Morris, 12/13/90)

50582-003; 045229: This document contains a summary of CDFA doc. #50582-023, rec. #090379. No worksheet was done (S. Morris 06/13/89).

50582-009; 048343: This document contains a summary of CDFA doc. #50582-023, rec. #090379. No worksheet was done (S. Morris 08/01/89).

TERATOLOGY, RAT

50582-015; 069793; "Teratogenic [sic] study of ethylene and propylene oxide and n-butyl acetate", contract no. 210-80-0013; Battelle, Pacific Northwest Laboratories, Richland, Washington; 05/82; propylene oxide, 100%, Aldrich lot # 1230 T E; Fifty female, Sprague-Dawley CD rats / treatment group were exposed by inhalation 7 hours / day for 5 days / week starting 3 weeks (day -15) before insemination (day +1) then every day through gestation day +16. The treatment groups were: (1) 0 ppm through day +16, (2) 0 ppm through day +6 then 500 ppm, (3) 0 ppm through day -1 then 500 ppm, and (4) 500 ppm through day +16. All rats were sacrificed on gestation day +21. Dams in groups 2-4 had marginally decreased food consumption and body weights. There were no significant treatment-related effects on reproductive or fetal developmental parameters. No adverse effect was indicated. The study was unacceptable and not upgradeable because sufficient maternal toxicity was not demonstrated (S. Morris, 10/04/89).

50582-023; 090380; James L. Schardein et al., "Inhalation Developmental Toxicity Study in Rats"; International Research and Development Corporation, Mattawan, MI, 10/26/87; propylene oxide, IRDC # 8863C, purity not stated; Twenty-five, mated (day 0) female CDF (Fisher 344) rats / group were exposed by inhalation to 0, 100, 300, or 500 ppm for 6 hours / day on gestation days 6-15 and sacrificed on day 20. Maternal food consumption and body weights were slightly decreased at 500 ppm. Maternal and developmental NOELs \geq 500 ppm. No dose-related effects were reported for fertility indexes or fetal malformations. Dose-related variations in fetal development of the 7th cervical rib were reported. No adverse effect was indicated. The study was unacceptable because of insufficient maternal toxicity but possibly upgradeable with submission of an adequate rationale for the high dose (S. Morris, 06/30/89, 03/14/91).

50582-016; 069794: This document contains a draft of the study at CDFA doc. # 50582-023, rec. # 090380. A worksheet was done (S. Morris, 06/30/89).

TERATOLOGY, RABBIT

50582-015; 069793; "Teratogenic study of ethylene and propylene oxide and n-butyl acetate", contract no. 210-80-0013; Battelle, Pacific Northwest Laboratories, Richland, Washington; 05/82; propylene oxide, 100%, Aldrich lot # 1230 T E; Eleven to 19, artificially-impregnated (day 0) female New Zealand White rabbits / group were exposed by inhalation 7 hours / day to 0 or 500 ppm on gestation days 1-19, or 0 ppm on days 1-6 then 500 ppm on days 7-19. All does were sacrificed on gestation day 30. Does exposed to 500 ppm on days 1-19 had slightly decreased food consumption and body weights and increased resorptions. No adverse effect was indicated. The study was unacceptable and not upgradeable because only one dose was used, clear maternal toxicity was not demonstrated, and there were not enough litters (S. Morris, 10/04/89, 12/19/90).

GENE MUTATION

50582-004; 041633; This document contains a paragraph from the introduction of CDFA doc. # 50582-001, rec. # 026429. It summarizes a number of genotoxicity studies. A possible adverse effect was indicated by reports of mutagenic effects in a variety of biological assays. No worksheet was done (S. Morris, 6/13/89).

50582-017; 069796; "Mutagenicity of and formation of oxygen radicals by trioses and glyoxal derivatives"; Yamaguchi, T. and Nakagawa, K. (1983): Agric. Biol. Chem., 47(11):2461-2465; propylene oxide, unstated purity; The Ames' assay was conducted with Σαλμονελλα τυπιμυριυμ TA 100. A possible adverse effect was indicated by the significant increase in revertant colonies at 350 ug/plate. The revertant rate was . 2X the spontaneous rate with S9 metabolic activation system from PCB-treated rats and . 6X without S9. The study is unacceptable and not upgradeable because there was no repeat trial (S. Morris, 07/03/89).

**** 50582-017; 069797;** "Mutagenic action of structurally related alkene oxides on Σχηζοσααχχαρουμπε πομπε: The influence, 'in vitro', of mouse-liver metabolizing system"; Migliore, L. et al. (1982): Mutation Research, 102:425-437; propylene oxide, purity not stated; Aliquots of 4 X 10⁶ cells of Σ. πομπε (strain P1) were incubated for 2-3 cell divisions (6 h) in the presence of 0, 3, 10, or 30 mM with or without S9 metabolic activation system from the livers of male, phenobarbitone-induced, Swiss albino mice. After plating and growth for 5 days, colonies were scored (white or sectorized vs red) for forward mutations in gene loci involved in the adenine pathway. A possible adverse effect was indicated by dose-related increases of mutation frequencies with and without S9. The study was acceptable (S. Morris, 07/05/89).

50582-017; 069798; "The mutagenic action of aliphatic epoxides"; Voogd, C. E. et al. (1981): Mutation Research, 89:269-282; propylene oxide, purity not stated, DMSO vehicle; The forward mutation rate of Κλεβσιελλα πνευμονιαε from streptomycin sensitive to resistant was measured after treatment with 0.0, 0.2, 0.5, or 1 mM. A possible adverse effect was indicated by a dose-related increase in mutation frequency. The study was unacceptable and not upgradeable

because of lack of metabolic activation system and many experimental details were omitted (S. Morris, 07/10/89).

50582-017; 069799; "Mutagenicity of ethylene oxide and propylene oxide and of the glycols and halohydrins formed from them during the fumigation of foodstuffs"; Pfeiffer, E. H. and Dunkelberg, H. (1980): *Fd. Cosmet. Toxicol.*, 18:115-118; propylene oxide, 99%, acetone vehicle; Rates were measured for mutation from histidine auxotrophy to prototrophy in Σαλμονελλα τυπιμυριυμ strains TA98, TA100, TA1535, and TA1537 treated with 10-200 umol/plate (actual concentrations not stated). A possible adverse effect was indicated by a dose-related increase in mutation frequencies in strains TA100 and TA1535. The study was unacceptable and not upgradeable because of lack of metabolic activation system and many experimental details were omitted (S. Morris, 10/04/89).

50582-017; 069800; "Assay of 855 test chemicals in ten tester strains using a new modification of the Ames test for bacterial mutagens"; McMahon, R. E. et al. (1979): *Cancer Research*, 39:682-693. This study was from the open literature. Mutagenic effects in bacteria were reported for propylene oxide. No worksheet was done because an adequate gene mutation study was on file with CDFA (S. Morris, 7/21/89).

50582-017; 069801; "Correlation of mutagenicity and 4-(p-nitrobenzyl)-pyridine alkylation by epoxides"; Hemminki, K. and Falck, K. (1979): *Toxicology Letters*, 4:103-106. This study was from the open literature. Mutagenic effects in bacteria were reported for propylene oxide. No worksheet was done because an adequate gene mutation study was on file with CDFA (S. Morris, 7/21/89).

50582-017; 069802; "Mutagenicity of aliphatic epoxides"; Wade, D. R. et al. (1978): *Mutation Research*, 58:217-223: This study was from the open literature. Mutagenic effects in bacteria were reported for propylene oxide. No worksheet was done because an adequate gene mutation study was on file with CDFA (S. Morris, 7/21/89).

50582-017; 069803; "Comparative studies of monoepoxides as inducers of reverse mutations in neurospora"; Kølmark, G. and Giles, N. H. (1955): Genetics, 40:890-902. This study was from the open literature. Mutagenic effects in fungi were reported for propylene oxide. No worksheet was done because an adequate gene mutation study was on file with CDFA (S. Morris, 7/24/89).

50582-017; 069807; "Mutagenic activity of propylene oxide in bacteria and mammalian systems"; Bootman et al. (1979): Mutation Research, 67:101-112. This study was from the open literature. Dose-related effects were not seen in a mouse dominant lethal assay. No worksheet was done because an adequate gene mutation study was on file with CDFA (S. Morris, 7/25/89).

50582-017; 069810; "Evaluation of propylene oxide for mutagenicity activity in 3 in vivo test systems"; Hardin, B. D. et al. (1983): Mutation Research, 117:337-344. This study was from the open literature. Treatment-related effects of propylene oxide were demonstrated in a sex-linked recessive lethal test in Αροσοπηλα μελανογαστερ. No worksheet was done because an adequate gene mutation study was on file with CDFA (S. Morris, 7/26/89).

CHROMOSOME EFFECTS

50582-004; 041635; This document contains a paragraph from the introduction of CDFA doc. # 50582-001, rec. # 026429. It summarizes a number of genotoxicity studies. A possible adverse effect was indicated by reports of chromatid aberrations in a variety of biological assays. No worksheet was done (S. Morris, 6/13/89).

50582-004; 041636; This document contains a paragraph from the introduction of CDFA doc. # 50582-001, rec. # 026429. It summarizes a sister chromatid exchange study. No adverse effect was indicated. No worksheet was done (S. Morris, 6/13/89).

50582-017; 069807; "Mutagenic activity of propylene oxide in bacterial and mammalian systems"; Bootman et al. (1979): Mutation Research 67:101-112; propylene oxide, 99.5% stated purity. Dividing, human peripheral lymphocytes were incubated for 24 hours with 0, 1.85, or 9.25 ug/ml with the addition of 0.4 ug/ml Colcemid for the last 3 hours. The cells were then harvested, fixed, Giemsa-stained, and microscopically examined for chromosome abnormalities. A **possible adverse effect** was demonstrated by treatment-related increases in chromosome aberrations other than gaps. The study was unacceptable because it lacked experimental details (S. Morris, 10/04/89).

50582-017; 069809; "Sister-chromatid exchange and chromosome aberrations in lymphocytes from monkeys exposed to ethylene oxide and propylene oxide by inhalation"; Lynch, D. W. et al. (1984): Toxicology and Applied Pharmacology, 76:85-95. This study was from the open literature. No dose-related changes in sister chromatid exchanges or chromosome aberrations were seen in monkeys exposed to 100 or 300 ppm propylene oxide 7 hours/day, 5 days/week for 2 years. No worksheet was done because adequate data are on file with CDFA to fill the data gap for a chromosome effects study (S. Morris, 7/26/89).

50582-017; 069810; "Evaluation of propylene oxide for mutagenicity activity in 3 in vivo test systems"; Hardin, B. D. et al. (1983): Mutation Research, 117:337-344. This study was from the open literature. Treatment-related effects of propylene oxide were not demonstrated in a dominant lethal assay in rats. No worksheet was done because adequate data are on file with CDFA to fill the data gap for a chromosome effects study (S. Morris, 7/26/89).

50582-017; 069811; "Mutagenicity study of workers exposed to alkylene oxides (ethylene oxide/propylene oxide) and derivatives"; Thiess A. M. et al. (1981): Journal of Occupational Medicine, 23:343-347. This study was from the open literature. Increased frequencies of chromosome aberrations were not demonstrated in lymphocytes from humans occupationally-exposed to alkylene oxides. No worksheet was done because adequate data are on file with CDFA to fill the data gap for a chromosome effects study (S. Morris, 7/26/89).

50582-017; 069812; "An in vitro chromosome assay using cultured rat-liver cells"; Dean, B. J. and Hodson-Walker, G. (1979): Mutation Research 64:329-337; propylene oxide, purity unstated; Cultured, rat-liver, epithelial cells were incubated for 24 hours with 0, 25, 50, 75, or 100 ug/ml followed by incubation in fresh medium for 24 hours with the addition of 0.3 ug/ml Colcemid for the last 2 hours. The cells were then harvested, hypotonically disrupted, fixed (methanol/acetic acid, 3:1), Giemsa-stained, and microscopically examined for chromosome abnormalities. A possible adverse effect was demonstrated by treatment-related increases in chromatid deletions and exchanges. The study was unacceptable because only one replicate was performed (S. Morris, 10/04/89).

SUMMARY: Although no single study is sufficient, the studies above collectively fill the data gap for a Chromosome Effects study and indicate a possible adverse effect.

DNA DAMAGE

50582-004; 041634; This document contains a paragraph from the introduction of CDFA doc. # 50582-001, rec. # 026429. It summarizes a number of genotoxicity studies. A possible adverse effect was indicated by reports of DNA alkylation and DNA strand breaks iv @irpo. No worksheet was done because an adequate DNA damage study was on file with CDFA (S. Morris, 6/13/89).

50582-004; 041637; This document contains a paragraph from the introduction of CDFA doc. # 50582-001, rec. # 026429. It summarizes a number of genotoxicity studies. A possible adverse effect was indicated by a report of a positive micronucleus test. No worksheet was done because an adequate DNA damage study was on file with CDFA (S. Morris, 6/13/89).

**** 50582-017; 069804;** "A reduced capacity for unscheduled DNA synthesis in lymphocytes from individuals exposed to propylene oxide and ethylene oxide"; Pero, R. W. et al. (1982): Mutation Research, 104:193-200; Unscheduled DNA synthesis (UDS) and ³H incorporation into DNA

were measured in freshly isolated human lymphocytes after treatment with [3]N-acetoxy-2-acetylaminofluorene. The DNA-repair proficiency index (DRPI) was defined as the ratio of UDS to 3H incorporation. A possible adverse effect was demonstrated by a significantly decreased DRPI of workers occupationally-exposed to propylene oxide. The study was acceptable (S. Morris, 7/24/89).

50582-017; 069807; "Mutagenic activity of propylene oxide in bacteria and mammalian systems"; Bootman et al. (1979): Mutation Research, 67:101-112. This study was from the open literature. No dose-related effects for propylene oxide were seen in a micronucleus assay. No worksheet was done because an adequate DNA damage study was on file with CDFA (S. Morris, 7/25/89)

50582-017; 069810; "Evaluation of propylene oxide for mutagenicity activity in 3 in vivo test systems"; Hardin, B. D. et al. (1983): Mutation Research, 117:337-344. This study was from the open literature. Treatment-related effects of propylene oxide were not demonstrated in a sperm morphology assay in mice. No worksheet was done because an adequate DNA damage study was on file with CDFA (S. Morris, 7/26/89).

NEUROTOXICITY

Not required at this time.

SUPPLEMENTAL INFORMATION

50582-017; 069795; "Toxic and mutagenic effects of ethylene oxide and propylene oxide on spermatogenic functions in cynomolgus monkeys"; Lynch, D. W. et al. (1983): The Toxicologist, 3(1):60; This document contains the abstract of a study of male monkeys exposed by inhalation to 0, 100, or 300 ppm, 7 hrs/day, 5 days/week for 24 months. Spermatogenic functions were

measured at the termination of exposures (10 monkeys) or 6 weeks later (44 monkeys). A possible adverse effect was indicated by decreased sperm counts and sperm motility. Also reported was an increase in an undefined variable, sperm drive range. No worksheet was done because this study did not conform to any guideline test-type (S. Morris, 7/3/89).

50582-017; 069808; "The influence of some alkylating agents on the structure of DNA in vitro"; Waller, S. A. S. (1974): Chem.-Biol. Interactions, 9:97-103. This study was from the open literature. Treatment of isolated calf thymus DNA with propylene oxide decreased the reversibility of denaturation of the DNA. No worksheet was done because this assay measured the physical-chemical properties of chemically-altered exogenous DNA and was not a "biological" assay (S. Morris, 7/25/89).

50582-017; 069805; "Detection of mutagen-induced lesions in isolated DNA using a new Βαχίλλος σφαιρίδιο transformation-based assay"; Phillips, A. R. et al. (1980): Mutation Research, 74:267-281. This study was from the open literature. Propylene oxide damage to isolated, bacterial DNA was detected by selecting for mutations resulting from recombination when bacteria of the same strain were transformed by the treated DNA. No worksheet was done because this assay measured the "mutagenic" properties of chemically-altered exogenous DNA and not the mutagenic properties of the test material (S. Morris, 7/24/89).

50582-017; 069806; "Detection of mutagen-induced lesions in isolated DNA marker rescue of Βαχίλλος σφαιρίδιο phage Δ 105"; Garro, A. J. and Phillips, A. R. (1980): Mutation Research, 73:1-13. This study was from the open literature. Propylene oxide damage to isolated, wild-type, phage DNA was detected as mutations in genes controlling plaque phenotype. No worksheet was done (S. Morris, 7/25/89).

50582-003; 041620: This document contained an excerpt from "IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man," (Vol. 11, pp. 194-196) which reviewed the open literature on health effects of propylene oxide. No worksheet was done (S. Morris, 8/4/89).

50582-018; 069813; "Environmental Health Criteria 56, Propylene Oxide"; United Nations Environment Programme, International Labour Organization, and World Health Organization, Geneva, Switzerland (1985). This monograph is a review of the open literature on health effects of propylene oxide. No worksheet was done (S. Morris, 8/1/89).

50582-018; 069814; "Chemical of current interest, propylene oxide: health and environmental effects profile"; Meylan, W. et al. (1986): Toxicology and Industrial Health, 2(3):219-258. This monograph is a review of the open literature on health effects of propylene oxide. No worksheet was done (S. Morris, 8/1/89).

END AUDIT

Records Examined for this Summary of Toxicology Data:

50582-001; 026429
50582-001; 026429
50582-003; 041620
50582-004; 041629
50582-004; 041633
50582-004; 041634
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50582-004; 041642
50582-004; 041643
50582-005; 042521
50582-003; 045229
50582-007; 045503
50582-007; 045504
50582-007; 045504
50582-009; 048443
50582-015; 069793
50582-015; 069793
50582-016; 069794
50582-017; 069795
50582-017; 069796
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50582-017; 069798
50582-017; 069799

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50582-017; 069801
50582-017; 069802
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50582-017; 069806
50582-017; 069807
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50582-017; 069807
50582-017; 069808
50582-017; 069809
50582-017; 069810
50582-017; 069810
50582-017; 069810
50582-017; 069811
50582-017; 069812
50582-018; 069813
50582-018; 069814
50582-023; 090379
50582-023; 090380

Worksheets in 12/19/90 package:

W069793.834

W090379.834

R901219

T901219